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STATE OF DELAWARE
BOARD OF PHARMACY

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PUBLIC MEETING NOTICE:	BOARD OF PHARMACY
DATE AND TIME:	Wednesday, August 19, 2015 9:30 am
PLACE:	Conference Room A, 2 nd Floor Cannon Building 861 Silver Lake Blvd., Dover, DE 19904
APPROVED:	September 16, 2015

MEMBERS PRESENT

Kenneth Sellers, Public Member, President
Susan Esposito, R.Ph., Professional Member, Vice President
Joli Martini, R.Ph., Professional Member
Kimberly Robbins, R.Ph., Professional Member
Tejal Patel, PharmD, Professional Member
Hooshang Shanehsaz, R.Ph., Professional Member
Bonnie Wallner, R.Ph., Professional Member
Julia Wheatley, Public Member
Jay Galloway, Public Member

MEMBERS ABSENT

DIVISION STAFF/DEPUTY ATTORNEY GENERAL PRESENT

David Dryden, Executive Secretary
Eileen Kelly, Deputy Attorney General
Christine Mast, Administrative Specialist III
Michelle McCreary, Pharmacist Compliance Officer

ALSO PRESENT

Scotti Russell
Tim Dillon
Natalie Hemphill
Suzanne Rabb-Long
Jaime Frink
Laura Hallisey
Kelsey Trichilo
Chris Evans
Matt Ven Dover
Keri Morgan
Nicholas Juliano
Jay Patel
Jeanne Criquani
Phil Anderson

Christina Ly
Cheryl Heiks
Elizabeth Ryan

CALL TO ORDER

Mr. Sellers called the meeting to order at 9:35 a.m.

REVIEW OF MINUTES

A motion was made by Ms. Martini and seconded by Ms. Patel, to approve the meeting minutes for June 17, 2015. The motion unanimously carried.

A motion to move ahead in the agenda to agenda item 5.0 was made by Ms. Martini seconded by Mr. Shanehsaz. The motion unanimously carried.

PRESIDENT'S REPORT

Mr. Sellers has enjoyed being president of the Board.

UNFINISHED BUSINESS

Complaint Status

13-09-11 – Assigned to Hearing Officer
13-12-11 – Assigned to Hearing Officer
13-19-11 – Forwarded to Office of Attorney General
13-01-13 – Forwarded to Office of Attorney General
13-04-13 – Forwarded to Office of Attorney General
13-05-13 – Forwarded to Office of Attorney General
13-06-13 – Forwarded to Office of Attorney General
13-20-13 – Forwarded to Office of Attorney General
13-26-13 – Assigned to Hearing Officer
13-01-14 – Forwarded to Office of Attorney General
13-03-14 – Assigned
13-04-14 – Assigned
13-05-14 – Assigned
13-06-14 – Forwarded to Office of Attorney General
13-07-14 – Forwarded to Office of Attorney General
13-08-14 – Assigned
13-09-14 – Forwarded to Office of Attorney General
13-10-14 – Forwarded to Office of Attorney General
13-11-14 – Forwarded to Office of Attorney General
13-12-14 – Forwarded to Office of Attorney General
13-13-14 – Assigned
13-14-14 – Forwarded to Office of Attorney General
13-15-14 – Assigned
13-16-14 – Assigned
13-17-14 – Assigned

Re-Review Proposal to Deny Hearing

Glenrock Medical Pharmacy, a motion was made to approve the application by Mr. Shanehsaz seconded by Mr. Galloway. The motion unanimously carried.

Consent Agreement Review

Anthony Ryan, a motion to accept the consent agreement as presented was made by Mr. Shanehsaz seconded by Mr. Galloway.

Thomas Kolakowski, a motion to accept the consent agreement as presented was made by Mr. Galloway seconded by Mr. Shanehsaz.

Statutory and Regulatory Discussion

- Practitioner/Pharmacy Ownership - No Report
- Provision for Disciplinary Action - No Report
- Pharmacy Technician Regulation - No Report
- Clarification of §2512(e)(f), Inactive Status - No Report
- Review of Crimes Listing – currently in review by the legislative committee

Application Requirements for Compounding Inspections Discussion

This is a standing agenda item that will be discussed later in the agenda during the NABP presentation.

NEW BUSINESS

Proposed Rules and Regulations Hearing

Ms. Kelly called the hearing to order. The Board members introduced themselves for the record. The purpose of the meeting is for the board to consider adoption of proposed amendments to rules and regulations. The proposed changes affect regulation 5.1.7 and 10.0. Ms. Kelly submitted exhibits of public hearing notices that were published in the Delaware State News and the News Journal. There being no written comment submitted during the 15 day comment window the hearing was adjourned. There being no public comments, Ms. Kelly asked that deliberations of proposed regulations be added to the September 16, 2015 agenda.

Mr. Sellers read into the record the following ratifications:

Pharmacist and Intern Licensure Approval Ratifications

Pharmacist:

A1-0004754	Andrew Gerard Babb
A1-0004755	Bethany Rae Sharpless
A1-0004756	Amanda Louise Valentin
A1-0004757	Hannah L. Parsons
A1-0004758	Adeola Olufunmilayo Edema
A1-0004759	Anik Palit
A1-0004760	Lawrence John Krebs
A1-0004761	Rachael Nicole DiMeo
A1-0004762	Tamika Marie Greenwood
A1-0004763	Babatunde Seun Bolarinwa
A1-0004764	Jeremy D. Hess
A1-0004765	Chelsea Ann Hawkins
A1-0004766	Jason W. Guy
A1-0004767	Daniel S. Hoffman
A1-0004768	Ferdinand Patrick Ngonga
A1-0004769	Julianne Deborah Gardner
A1-0004770	Kemeisha N. Taylor
A1-0004771	Sarah Catherine Maheady
A1-0004772	Jordan R. VanAuken
A1-0004773	Patrick C. Kupcha
A1-0004774	Kenneth Calvin Wiley
A1-0004775	Rebecca Lynn Pepper
A1-0004776	Judy E. Balcombe
A1-0004777	Robert Lee Curtis Okwemba
A1-0004778	Leah J. Milton

A1-0004779	Jennifer Lyn Murray
A1-0004780	Ye Chan Yoon
A1-0004781	Richard J. Debartolo
A1-0004782	Zhiwei Mai
A1-0004783	David N. Lewinter
A1-0004784	Alexis Hannah Gross
A1-0004785	Anjana Patel
A1-0004786	Gayleen Anyango Philips
A1-0004787	Yu Song
A1-0004788	Kenza Zahri Elliott
A1-0004789	Jennifer Kim Do
A1-0004790	Hasan Khairullah atta Al Hasani
A1-0004791	Antonella S. Frattarelli
A1-0004792	Debra A. Remner
A1-0004793	Tram Anh Dan
A1-0004794	Gillian Ndi
A1-0004795	Nicholas James Szalejko
A1-0004796	Tiffany Tess Liu
A1-0004797	Marija Ruzic
A1-0004798	Seth Joel Aaron
A1-0004799	JungMin Hwang
A1-0004800	Costadina Aneziris
A1-0004801	Allegra Kate Spiezio
A1-0004802	Bhaves Rameshbhai Patel
A1-0004803	Thomas Joseph Crum
A1-0004804	Jarjeet Giovonni Singh

A motion was made by Ms. Esposito and seconded by Ms. Patel to approve the ratification of the Pharmacist applications. The motion unanimously carried.

Pharmacist Intern:

A7-0002398	Latrina Denise Melton
A7-0002399	Jigar J. Patel
A7-0002400	Siyuan Liu
A7-0002401	Newell Wellington Craft
A7-0002402	Sangwon Jeon
A7-0002403	Kristin Elizabeth Talley

A motion was made by Ms. Robbins and seconded by Ms. Patel to approve the ratification of the Pharmacist Intern applications. The motion unanimously carried.

Non-Resident Pharmacy Licensure Approval Ratifications

A9-0001653 Liberty Medical, LLC d/b/a Liberty Medical Supply
A9-0001654 OHM Pharmacy Services Inc
A9-0001655 Manhasset Park Drug Corp
A9-0001656 Cloverland Drugs Inc
A9-0001657 IHC Health Services Inc
A9-0001658 Cardinal Health 128, LLC dba MMS Solutions
A9-0001659 Med-Care Inc.
A9-0001660 Biorx LLC
A9-0001661 BioRx
A9-0001662 CareZone Pharmacy
A9-0001663 Macdill Pharmacy

A9-0001664 Jefferson Pharmacy LLC
A9-0001665 Trinity Pharmacy Services/Lehigh Valley LLC
A9-0001666 BrivoRx of Nevada, LLC
A9-0001667 Armour Pharmacy
A9-0001668 Professional Compounding Pharmacy
A9-0001669 Freedom Pharmacy
A9-0001670 First Health Specialty Pharmacy Inc
A9-0001671 Davidson Discount Pharmacy, Inc.
A9-0001672 RPH Partners, LLC dba Prescription Mart
A9-0001673 Capital RX Pharmacy Dept, LLC
A9-0001674 Catamaran Home Delivery
A9-0001675 Custom Compounding Pharmacy, LLC
A9-0001676 Orchard Pharmaceutical Services, LLC
A9-0001677 Reliable Pharmacy, LLC
A9-0001678 Primary Care Pharmacy

A motion was made by Mr. Shanehsaz and seconded by Ms. Patel to approve the ratification of the Non-Resident Pharmacy applications. The motion unanimously carried.

Wholesale Distributor Licensure Approval Ratifications

A4-0001899 Boehringer Ingelheim Vetmedica, Inc
A4-0002105 A.P.I. Solutions, Inc.
A4-0002209 Par Sterile Products, LLC
A4-0002210 Crown Laboratories, Inc.
A4-0002211 American Pharmaceutical Ingredients, LLC
A4-0002213 The Procter & Gamble Distributing LLC
A4-0002214 Enclara Pharmacia-Wholesale
A4-0002215 Profounda, Inc.
A4-0002216 SCA Pharmaceuticals, LLC
A4-0002217 The Procter & Gamble Distributing LLC
A4-0002218 Metrics Inc. d/b/a Mayne Pharma
A4-0002219 Wal-Mart Pharmacy Warehouse 45
A4-0002220 Henry Schein Animal Health
A4-0002221 Intermed Distributors, Inc.
A4-0002222 Den-Mat Holdings, LLC
A4-0002223 Dental Health Products, Inc.
A4-0002224 B & B Pharmaceuticals, Inc.
A4-0002225 The Hilsinger Company, DBA HILCO
A4-0002226 Pharmaceutical Credit Company, LLC
A4-0002227 Pharma Genetico LLC
A4-0002228 Ritedose Pharmaceuticals, LLC
A4-0002229 Cypress Medical Products, LLC
A4-0002231 Alvix Laboratories LLC
A4-0002232 BioRx

A motion was made by Mr. Shanehsaz and seconded by Ms. Patel to approve the ratification of the Wholesale Distributor applications. The motion unanimously carried.

Medical Gas Dispensers

A2-0000131 Florida Home Medical Supply
A2-0000132 Advanced Medical Homecare Supplies, Inc.

A motion was made by Mr. Shanehsaz and seconded by Ms. Patel to approve the ratification of the Medical Gas Dispensers applications. The motion unanimously carried.

Retail Pharmacy Licensure Approval Ratification
A3-0000987 Delaware CVS Pharmacy, LLC

A motion was made by Mr. Shanehsaz and seconded by Ms. Patel to approve the ratification of the Retail Pharmacy applications. The motion unanimously carried.

Retail Pharmacy Temporary Licensure Approval Ratification
None
Outsourcing Facility

AA-0000008 PharMedium Services, LLC
AA-0000009 PharMedium Services, LLC
AA-0000010 PharMedium Services, LLC
AA-0000011 PharMedium Services, LLC

A motion was made by Mr. Shanehsaz and seconded by Ms. Patel to approve the ratification of the Outsourcing Facility applications. The motion unanimously carried.

Pharmacist-In-Charge Interviews

Ms. Robbins conducted PIC interviews with:
Natalie Hemphill, Harris Teeter #327
Laura Hallisey, CVS #10103 Newark, DE
Nicholas Julianna, CVS #10609 Wilmington, DE*
Christopher Evans, Super Fresh Claymont DE.*

Board Review of Hearing Officer Recommendation

Timothy Dillon Hearing Office Recommendation was reviewed by the board. A motion to approve the recommendation as presented was made by Mr. Galloway seconded by Mr. Shanehsaz. The motion carried with Ms. Wallner recusing herself from the motion.

Board Review of Applications by DAG

Care Direct Rx, a motion to approve was made by Ms. Robbins seconded by Ms. Patel. The motion carried.
Trilogy Pharmacy, a motion to propose to deny was made by Mr. Shanehsaz seconded by Ms. Robbins. The motion carried unanimously.

Anazao Health Corp., a motion to approve was made by Mr. Shanehsaz seconded by Ms. Robbins. The motion carried unanimously.

Prescription Care Pharmacy, a motion to approve was made by Mr. Galloway seconded by Ms. Martini. The motion carried unanimously.

Cantrell Drug Co., a motion to table was made by Ms. Robbins seconded by Ms. Patel. The motion carried unanimously.

Trigen Laboratories, a motion to table was made by Ms. Esposito seconded by Ms. Robbins. The motion carried unanimously.

Rx Care Providers Corp., a motion to approve was made by Ms. Esposito seconded by Ms. Robbins. The motion carried unanimously.

IV Solutions of Lubbock, a motion to table was made by Ms. Esposito seconded by Ms. Wheatley. The motion carried unanimously.

South Coast Specialty Compounding, a motion to approve was made by Ms. Robbins seconded by Mr. Galloway. The motion carried unanimously.

Best Care Pharmacy, a motion to approve was made by Ms. Robbins seconded by Mr. Galloway. The motion carried unanimously.

Blessings International, a motion to table was made by Ms. Esposito seconded by Ms. Robbins. The motion carried unanimously.

Homescripts.com LLC., a motion to approve was made by Ms. Robbins seconded by Ms. Patel. The motion carried unanimously.

Doctor's Specialty Pharmacy, a motion to table was made by Mr. Shanehsaz seconded by Ms. Esposito. The motion carried unanimously.

Empire Specialty Pharmacy, a motion to table was made by Ms. Esposito seconded by Ms. Patel. The motion carried unanimously.

Lisa White, a motion to approve was made by Mr. Shanehsaz seconded by Ms. Martini. The motion carried unanimously.

Continuing Education Approval

Brooke Darmstadter, a motion to table was made by Ms. Esposito seconded by Mr. Shanehsaz. The motion carried unanimously.

NABP Completed Inspections – NABP "VAWD"

A motion to combine 5.9 and 5.11 of the agenda a motion was made by Ms. Robbins seconded by Ms. Patel. The motion carried.

Pharmacist Dispensing of Syringes

Mr. Dryden reported that regulation 5.1.0 would allow a pharmacist to provide syringes to the consumer for use with prescriptive medications. This regulation does not allow the pharmacist to provide syringes for use of non-prescribed medications.

National Boards of Pharmacy (NABP) Presentation – Scotti Russell

Scotti Russell from NABP presented the board with information on the following topics: Verified Pharmacy Program (VPP) was developed to assist boards in verification of inspection and compliance of compounding and non-compounding non-resident pharmacies. The home state can upload their inspection reports for other states to review and make an informed decision on licensing of that non-resident pharmacy. The VPP is also increase uniformity of minimum inspection criteria by all states which will lead to acceptance of a states's inspection processes by all other states. VPP inspection services are provided by NABP for a cost. They are unannounced for compounding and non-compounding pharmacies. The costs are formulated based solely on costs of the inspection related to manpower needed to complete the inspection. Fees vary depending on the type of inspection required. Delaware Inspection reports can be uploaded to NABP to be shared with other states.

COMMITTEE REPORTS

Legislative – Joli Martini, Jay Galloway, Kim Robbins, Tejal Patel, Hooshang Shanehsaz and David Dryden

Mr. Dryden informed the board that HB38 w/HA 1 + SA 1 was signed by the Governor on June 30, 2015. The effective date of the bill is September 28, 2015.

Continuing Education – Joli Martini, Bonnie Wallner, Tejal Patel and David Dryden:

No Report

Consumer Affairs – Ken Sellers, Jay Galloway and Julia Wheatley

No Report

Professional Liaisons – Kim Robbins and Tejal Patel:

Liz Ryan from DPS reported that they have not met since June 2015. The next scheduled meeting is September 15, 2015. They are in the planning stages of upcoming training events.

Controlled Substance Liaisons – Kenneth Sellers, Tejal Patel, Jay Galloway and David Dryden:

Mr. Dryden reported that the committee has been working on proposed Safe Opioid Prescribing proposed regulations. There was a hearing scheduled and held. The committee has received written comment; they will deliberate during the next scheduled meeting to be held on September 23, 2015.

Patient Safety Committee – Michelle McCreary (Chair), Kenneth Sellers, Tejal Patel, Kimberly Robbins, Susan Esposito, Joli Martini, Hooshang Shanehsaz, Jay Patel

Michelle McCreary had no report. The next scheduled meeting is September 16, 2015.

COMMITTEE UPDATES REGARDING PROPOSED REGULATIONS

USP 795 & 797 Committee – Tejal Patel, Brenda Pavlic, Hooshang Shanehsaz, Calvin Freedman and David Dryden:

No Report

Collaborative Care Committee – Bonnie Wallner, Cheri Briggs, Cheryl Heiks, Drew Wilson, Deborah Hamilton, Joli Martini, Julie Miro-Wenger, Mark Thompson, Mike Perza, Nick Biasotto, Pooja Dogra, Tejal Patel, Terri Corbo, William Harbester, David Dryden:

No Report

BOARD CORRESPONDENCE

Mr. Dryden provided the board with the following correspondence in the form of handouts:

NABP – Continue Legacy of Innovations in Test Development

NABP - VAWD-Accredited Wholesale Distributors

NABP - VAWD-Accredited Third-Party Logistics Providers

NABP - Internet Drug Outlet Identification Program

NABP - VPP Update 30July2015

Pharmacist Substitution of Biological Products

NABP – Adoption of Medication Synchronization*

NABP – Meningitis Outbreak, OR*

EXECUTIVE SECRETARY, INSPECTION & PMP REPORT - David Dryden, Michelle McCreary, Samantha Nettesheim

Mr. Dryden reported that he attended the annual FDA meeting. He will be working on the 20.88 credential. The DPS pilot for medication disposal will begin in the near future. The disposal will occur by the patient through a envelope system that chemical destroys the medication for safe disposal in the trash.

Ms. McCreary reported that she has completed the following inspections for July and August:

1 – Sterile Compounding Inspection which required 3 visits, 2 visits with the DEA

15 – Routine Inspections which resulted in 1 call back with the DEA.

2 - Remodel Inspections

1 – Narcotic Treatment Facility Inspection with the DEA

1 – Pre-Inspection

1 – Re-Inspection due to violations from June inspection

1 – Investigation

1 – Closing Inspection

A motion to amend the agenda to include the Election of Officers was made by Ms. Martini seconded by Mr. Shanehsaz. The motion to amend the agenda carried unanimously.

Ms. Wallner was nominated for President of the Board by Ms. Robbins. Ms. Wallner respectfully declined.

Ms. Esposito was nominated for President of the board by Ms. Martini. Ms. Esposito accepted the nomination. A motion to appoint Ms. Esposito President of the Board was made by Ms. Martini seconded by Mr. Shanehsaz. The motion carried unanimously.

Mr. Shanehsaz was nominated for Vice President of the board by Ms. Esposito. Mr. Shanehsaz accepted the nomination. A motion to appoint Mr. Shanehsaz Vice President of the Board was made by Ms. Esposito seconded by Ms. Robbins. The motion carried unanimously.

NEWSLETTER UPDATES

The August newsletter has been released and is available.

OTHER BUSINESS BEFORE THE BOARD

None

PUBLIC COMMENT

None

NEXT SCHEDULED MEETING

The next meeting is scheduled for September 16, 2015 at 9:30 Am., Conference Room A 2nd floor.

ADJOURNMENT

There being no other business before the Board a motion to adjourn the meeting was made by Ms. Martini, seconded by Ms. Patel at 12:12 pm.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Mast", written in a cursive style.

Christine Mast
Administrative Specialist III
Liaison, Board of Pharmacy